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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/083,198 | 05/22/98 | BRINGI | V 021653.0138 |

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EXAMINER

MARX, I

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1651

DATE MAILED: 04/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/083,198

Applicant(s)

Bringi

Examiner

Irene Marx

Group Art Unit

1651



☒ Responsive to communication(s) filed on Jan 26, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3, 6-21, and 24-72 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 6-21, and 24-72 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 16

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The application should be reviewed for errors.

The amendment after final amendment filed January 26, 2001 is acknowledged and entered. Claims 1-3, 6-21, and 24-72 are being considered on the merits.

The finality of the last action is withdrawn in view of the new grounds of rejection below.

Table 2 should be replaced. The last line thereof is illegible. A corrected table is not of record..

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6-21, and 24-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 18 respectively 24-26 and 72 are inconsistent, inasmuch as claims 2 and 18 are phrased in the alternative. The replacement of "and" with --or-- in claims 24-26 and 72 would be remedial..

Claim 1 is confusing in that the term --or-- is missing before "an" at line 7 of claim 1. It is noted that the claim is directed to "an alkyl esters thereof", which is grammatically incorrect. In the event that "and" is the desired term, it is apparent that both of jasmonate-related compounds and alkyl esters are required.

Claim 27 fails to find antecedent basis in claims 1 or 18 for "silver" or for "jasmonic acid".

With respect to the addition of β -phenylalanine in claim 72, the amount required for the desired effect is queried. It is noted that applicant points to page 25 of the specification for support of this compound as a biosynthetic precursor of taxane production. However, a disclosure regarding the amount required for this purpose is not clearly found at the indicated page of the specification. It is unclear that the required effect is obtainable when a trace amount, such as 0.0001% or less of the compound is added to media.

In claim 15, "ACC" should be spelled out to clarify the claim.

In claim 29 and 34, the nature of "SKF-525A" is queried. This does not appear to be an art recognized term. Correction is required. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim 30 is inconsistent with claim 1, regarding the enhancement class "jasmonic acid or an alkyl ester thereof".

Claim 50 is vague, indefinite and confusing in the recitation of "exchanging nutrient medium." Note the amendment made to claim 49.

Claims 43-48 are confusing in the recitation of "saccharide". If "a saccharide" is intended, the claims should be amended accordingly.

Claims 32 remains confusing in the recitation of "auxin-related growth regulator". Amendment to include the compounds of claim 38 would be remedial.

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant's indication that claim 72 should be allowed is acknowledged. Please note the rejection under 35 U.S.C § 112, supra.

From applicant's explanation it is apparent that just the second medium "induces taxane production". From dependent claim 49 it is still unclear which of the media is replenished periodically. Is it the first or the second or both? (Response, page 4).

Applicants explanations regarding the claim language fail to obviate the indefiniteness in claim 43 regarding the amount intended by "lower" and "higher". Is the difference 0.00001%, 0.0001%, 1%, 10%, 50%, 90%? (Response, page 4).

It is noted that applicant did not address the criticism regarding the use of "saccharide" in claims 43-48.

With respect to "auxin-related growth regulator" it is noted that no clear definition is found in the specification, even though a few examples are proffered. It is unclear from the context whether the relationship to auxin is close or far. That auxins are a well known class of

compounds is not disputed. However, that the terminology "auxin-related growth regulator" has been used in the art does not clearly define the compounds intended as "auxin-related" in the current claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 68 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Christen *et al.*.

The claims are directed to a method of producing one or more taxanes in cell culture of *Taxus* species in suspension wherein the nutrient medium comprises amino acids.

Christen *et al.* discloses to a method of producing one or more taxanes in cell culture of *Taxus* species in suspension wherein the nutrient medium comprises amino acids. See, e.g., Example 4 for the use of Gamborg B5 including casamino acids (Tables I and II).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196 .



Irene Marx
Primary Examiner
Art Unit 1651